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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,352	11/02/2001	Keith Tanner	RPS6097-US	3443

7590
Donald O. Nickey
Cardinal Health, Inc.
7000 Cardinal Place
Dublin, OH 43017

04/25/2003

EXAMINER

LEYSON, JOSEPH S

ART UNIT	PAPER NUMBER
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1722

DATE MAILED: 04/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,352

Applicant(s)

TANNER ET AL

Examiner

Joseph Leyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to an apparatus, classified in class 425, subclass 378.1.

II. Claim 19, drawn to a method, classified in class 264, subclass 176.1.

III. Claims 20 and 21, drawn to an apparatus, classified in class 425, subclass 327.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another materially different apparatus, such as an apparatus without a casting drum; or the apparatus as claimed can be used to practice another and materially different process, such as a process which melts a material which is not a liquid gel mass.
3. Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be

shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another materially different apparatus, such as an apparatus without a casting drum; or the apparatus as claimed can be used to practice another and materially different process, such as a process which melts a material which is not a liquid gel mass.

4. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the extrusion device being tilted. The subcombination has separate utility such as extrusion of material wherein the material is not provided by means for melting the material on demand.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by

their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Donald O. Nickey on 4 April 2003, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The title and abstract should be amended to reflect the elected invention, i.e., apparatus only.

9. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required.

See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

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It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

10. The disclosure is objected to because of the following informalities: The specification should be checked for proper idiomatic language, for proper spelling, and/or for proper numerical designations. See for example the following:

<u>pp.</u>	<u>lines</u>	<u>i.e.</u>
11	9	delete "15"
11	13-14	"to dispose between said means to melt said solid polymer" should be --disposed between said means to melt said solid polymer and said extrusion device--
18	19	"10" should be --100--

Appropriate correction is required.

11. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the reservoir means disposed between the means to melt the polymer and the extrusion device, as recited by claims 11 and 15; and the manifold disposed between the reservoir and the extrusion device, as recited by claims 14 and

18, must be shown or the feature(s) canceled from the claim(s).

No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

12. Claim 11 and 18 are objected to because of the following informalities:

in claim 11, "said polymer" should be --said film-forming material-- for claim clarity;

in claim 18, "said reservoir" should be --said reservoir means-- for claim clarity.

Appropriate correction is required.

13. Claims 2-5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2-5 only further recite product recitations which do not further limit the structure or structural relationships of the apparatus of claim 1. Such product recitations only relate to the intended use of the claimed apparatus.

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14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is indefinite because it is unclear whether "said reservoir" is referring to the reservoir means of claim 11 or some other reservoir. The examiner suggests making claim 14 dependent upon claim 11 and changing "said reservoir" in claim 14 to --said reservoir means--.

Claim 15 recites "to dispose between said means to melt said solid polymer" which is indefinite as to its metes and bounds because "between" must have at least two reference points, i.e., between A and B. The examiner suggests changing it to --disposed between said means to melt said solid polymer and said extrusion device--.

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1-5, 9, 10 and 12 are rejected under 35

U.S.C. 102(b) as being anticipated by Herridge et al.(-922).

Herridge et al.(-922) teach an apparatus, that corresponds to the instant apparatus, which includes a casting drum 160, means for melting solid film-forming material on demand defined by a drum unloader (col. 8, lines 6-12; col. 14, lines 35-46), pump means defined by a gear pump for transporting melted material (col. 8, lines 6-12; col. 14, lines 42-45) and an extrusion device 140 with a chamber and an extrusion slot (col. 7, line 54, to col. 8, line 61). Note that recitations, such as "suitable for encapsulation from a solid film-forming material", "wherein said film-forming material has an aqueous component", "wherein said film-forming material comprises at least one component selected from the group consisting of starch, gelatin, carrageenans, gums and synthetic materials", "wherein said film-forming material comprises iota-carrageenan and modified starch; water; a plasticizer; and a buffer" and "wherein said film-forming material comprises gelatin, water and plasticizers", relate to the intended use of the claimed apparatus. Intended use has been continuously held not to be germane to determining the patentability of the apparatus, In re Finsterwalder, 168

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USPQ 530. Purpose to which apparatus is to be put and expression relating apparatus to contents thereof during intended operation are not significant in determining patentability of an apparatus claim, Ex parte Thibault, 164 USPQ 666. Inclusion of the material worked upon by a structure being claimed does not impart patentability to the claims, In re Otto et al., 136 USPQ 458. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitation of that claimed, Ex parte Masham, 2 USPQ 2d 1647.

18. Claims 1-5, 9-12, 14-16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Doesburg et al.(-958).

Doesburg et al.(-958) teach an apparatus, that corresponds to the instant apparatus, which includes a casting drum 28, means for melting solid film-forming material on demand defined by a drum unloader 38, pump means defined by a gear pump 34 for transporting melted material, an extrusion device 30 with a chamber and an extrusion slot (col. 6, lines 47-67), a reservoir 32 disposed between the drum unloader 38 and the extrusion device 30, and a manifold in which the gear pump 34 is located (col. 6, lines 25-26) disposed between the reservoir 32 and the extrusion device 30. Note that recitations, such as "suitable

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for encapsulation from a solid film-forming material", "wherein said film-forming material has an aqueous component", "wherein said film-forming material comprises at least one component selected from the group consisting of starch, gelatin, carrageenans, gums and synthetic materials", "wherein said film-forming material comprises iota-carrageenan and modified starch; water; a plasticizer; and a buffer", "wherein said film-forming material comprises gelatin, water and plasticizers" and "for applying a polymer to a substrate", relate to the intended use of the claimed apparatus. Intended use has been continuously held not to be germane to determining the patentability of the apparatus, *In re Finsterwalder*, 168 USPQ 530. Purpose to which apparatus is to be put and expression relating apparatus to contents thereof during intended operation are not significant in determining patentability of an apparatus claim, *Ex parte Thibault*, 164 USPQ 666. Inclusion of the material worked upon by a structure being claimed does not impart patentability to the claims, *In re Otto et al.*, 136 USPQ 458. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitation of that claimed, *Ex parte Masham*, 2 USPQ 2d 1647.

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Herridge et al.(-922) or Doesburg et al.(-958) in view of Majkrzak(-308).

Herridge et al.(-922) and Doesburg et al.(-958) each substantially disclose the apparatus as mentioned above, except

for the means for melting including a melting grid above the solid forming material.

Majkrzak(-308) discloses that a drum unloader generally includes a melting grid above the solid forming material (col. 1, line 50, to col. 2, line 2).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the drum unloader of either Herridge et al.(-922) or Doesburg et al.(-958) with a melting grid above the solid forming material because it is well known and conventional for a drum unloader to include such a melting grid for melting the solid forming material, as disclosed by Majkrzak(-308).

22. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Herridge et al.(-922) or Doesburg et al.(-958) in view of Davies et al.(-147).

Herridge et al.(-922) and Doesburg et al.(-958) each substantially disclose the apparatus as mentioned above, except for the means for melting including a melting grid below the solid forming material.

Davies et al.(-147) disclose means for melting solid forming material on demand including a melt grid 37 below the solid forming material, an extrusion devices 97, pump means defined by a gear pump 47 for transporting the melted forming

material to the extrusion devices 97, a reservoir 67 disposed between the melt grid 37 and the extrusion devices 97 for pooling the melted forming material, and a manifold disposed between the reservoir 67 and the extrusion devices 97 for feeding the melted forming material to the extrusion devices 97 (col. 8, lines 33-35; fig. 1). Note that the feedrate of the solid forming material is varied, thus providing the material on demand, by controlling the rotation of a screw conveyor 3 of the means for melting (col. 7, line 25, to col. 8, line 33).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the melting means of either Herridge et al.(-922) or Doesburg et al.(-958) with the melting means of Davies et al.(-147) because such melting means including a melting grid is a well known art recognized alternative means for melting material to be supplied to an extrusion device as disclosed by Davies et al.(-147).

23. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Herridge et al.(-922) or Doesburg et al.(-958) in view of Dukert et al.(-997).

Herridge et al.(-922) and Doesburg et al.(-958) each substantially disclose the apparatus as mentioned above, except for the extrusion device being a coat hangar die.

Dukert et al.(-997) disclose that well known extrusion devices for extruding film or sheets include conventional flat sheet dies, slit dies or coat hangar dies (col. 1, lines 21-28).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to further modify the extrusion device of either Herridge et al.(-922) or Doesburg et al.(-958) with a coat hangar die because such a coat hangar die is a well known and conventional art recognized alternative means for making a film or sheet, as disclosed by Dukert et al.(-997).

24. Claims 1-6, 8-12, 14-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hay, II(-016) in view of Davies et al.(-147) and Vollbrecht et al.(-718).

Hay, II(-016) discloses an apparatus for preparing films including a casting drum 15, means for melting solid film-forming material, such as polymer (col. 1, lines 5-9), defined by an extruder 11, and an extrusion device 12 with a chamber and an extrusion slot (col. 2, lines 12-16). However, Hay, II(-016) does not disclose means for melting the solid film-forming material on demand or pump means.

Davies et al.(-147) disclose means for melting solid forming material on demand including a melt grid 37 below the solid forming material, an extrusion devices 97, pump means

defined by a gear pump 47 for transporting the melted forming material to the extrusion devices 97, a reservoir 67 disposed between the melt grid 37 and the extrusion devices 97 for pooling the melted forming material, and a manifold disposed between the reservoir 67 and the extrusion devices 97 for feeding the melted forming material to the multiple extrusion devices 97 (col. 8, lines 33-35; fig. 1). Note that the feedrate of the solid forming material is varied, thus providing the material on demand, by controlling the rotation of a screw conveyor 3 of the means for melting (col. 7, line 25, to col. 8, line 33).

Vollbrecht et al.(-718) disclose an extrusion device 10, 11 and means for melting solid forming material and supplying the melted forming material to the extrusion device 10, 11 defined by an extruder 1. Vollbrecht et al.(-718) disclose that an alternative form of a melting means, instead of the extruder 1, is a melting grid (col. 5, lines 45-51).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the apparatus of Hay, II(-016) with the melting means, pump means, reservoir and/or manifold of Davies et al.(-147) because such melting means including a melting grid is a well known art recognized alternative means for melting material to be supplied to an

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extrusion device as disclosed by Davies et al.(-147) and Vollbrecht et al.(-718), because such pump means would transport melted material to the extrusion device, because such a reservoir would pool the melted material, and/or because such a manifold would enable supply of melted material to multiple extrusion devices. Note that recitations, such as "suitable for encapsulation from a solid film-forming material", "wherein said film-forming material has an aqueous component", "wherein said film-forming material comprises at least one component selected from the group consisting of starch, gelatin, carrageenans, gums and synthetic materials", "wherein said film-forming material comprises iota-carrageenan and modified starch; water; a plasticizer; and a buffer", "wherein said film-forming material comprises gelatin, water and plasticizers" and "for applying a polymer to a substrate", relate to the intended use of the claimed apparatus. Intended use has been continuously held not to be germane to determining the patentability of the apparatus, In re Finsterwalder, 168 USPQ 530. Purpose to which apparatus is to be put and expression relating apparatus to contents thereof during intended operation are not significant in determining patentability of an apparatus claim, Ex parte Thibault, 164 USPQ 666. Inclusion of the material worked upon by a structure being claimed does not impart patentability to

the claims, In re Otto et al., 136 USPQ 458. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitation of that claimed, Ex parte Masham, 2 USPQ 2d 1647.

25. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hay, II(-016) in view of Davies et al.(-147) and Vollbrecht et al.(-718) as applied to claims 1-6, 8-12, 14-16 and 18 above and further in view of Dukert et al.(-997).

Dukert et al.(-997) disclose that well known extrusion devices for extruding film or sheets include conventional flat sheet dies, slit dies or coat hangar dies (col. 1, lines 21-28).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to further modify the extrusion device of Hay, II(-016) with a coat hangar die because such a coat hangar die is a well known and conventional art recognized alternative means for making a film or sheet, as disclosed by Dukert et al.(-997).

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Upton et al.(-233), Klenk et al.(-493), Johannes et al.(-537), Doesburg et al.(-639) and Muskalla et al.(-904) are cited as of interest.


27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Leyson whose telephone number is (703) 308-2647. The examiner can normally be reached on M-F(8:30-6:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker can be reached on (703) 308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

jl

jl
April 16, 2003


JAMES P. MACKEY
PRIMARY EXAMINER

4/18/03